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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61B 17/06		A2	(11) International Publication Number: WO 99/22650
			(43) International Publication Date: 14 May 1999 (14.05.99)
<p>(21) International Application Number: PCT/GB98/03263</p> <p>(22) International Filing Date: 2 November 1998 (02.11.98)</p> <p>(30) Priority Data: 9722939.7 31 October 1997 (31.10.97) GB</p> <p>(71) Applicant (for all designated States except US): THE UNIVERSITY COURT OF THE UNIVERSITY OF DUNDEE [GB/GB]; Dundee DD1 4HN (GB).</p> <p>(72) Inventors; and</p> <p>(75) Inventors/Applicants (for US only): CUSCHIERI, Alfred [GB/GB]; Denbrae Mill, Strathkiness Low Road, St. Andrews, Fife K19 9TY (GB). FRANK, Graham, Timothy [GB/GB]; 37 Naughton Road, Wormit, Newport-on-Tay, Fife DD6 8NG (GB).</p> <p>(74) Agent: MURGITROYD & COMPANY; 373 Scotland Street, Glasgow G5 8QA (GB).</p>			<p>(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p> <p>Published Without international search report and to be republished upon receipt of that report.</p>
<p>(54) Title: DEVICE FOR ENDOSCOPIC DELIVERY OF SURGICAL MATERIAL</p> <p>(57) Abstract</p> <p>A device for the delivery of a shape memory securing member into a confined space, the device having an exit for the securing member and means to move the securing member through the exit, the device further including a magazine having a plurality of channels each of which can store a securing member is described. Preferably, each securing member is restrained in the device in a first configuration, and upon passing through the exit adopts a second configuration. One form of the magazine is a barrel. The barrel may be rotatable around an axis, and the channels can be disposed parallel to said axis or may lie in a helical configuration. This arrangement can be likened to a "revolver barrel" on a firearm. One advantage of the present invention in surgery is that it can store several sutures or ligatures to allow multiple placements without the need to withdraw the instrument from the patient.</p>			

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1 DEVICE FOR ENDOSCOPIC DELIVERY OF SURGICAL MATERIAL

2

3 This invention relates to a delivery device.

4

5 Minimal access surgery (MAS) allows certain operations
6 to be carried out through small access holes thus
7 avoiding the creation of large traumatic wounds.

8 However difficulties arise in suturing surgical
9 incisions and ligating inside the patient using current
10 instruments due to the small size of the access hole
11 which restricts movement of the instrument. Tying
12 knots in suture and ligating threads is particularly
13 difficult and time consuming.

14

15 In an attempt to overcome this problem, devices have
16 evolved for manipulating needles within the body. One
17 such device (disclosed in WO92/05828) comprises a
18 cannula which may be inserted into the body through a
19 narrow opening. The cannula houses a piston which is
20 slidable within the cannula and manipulates a needle.
21 The needle is retained inside the cannula during
22 insertion of the cannula into the patient. The needle
23 is formed from elastic material and when retained
24 inside the cannula, the needle is held in a generally

1 straightened configuration. When the cannula is in
2 place, the needle can then be projected from the end of
3 the cannula to penetrate tissues and join wounds.
4 Other items such as ring clips can be manipulated using
5 the device. Several needles can be stored in the
6 device in a straightened configuration. In such a
7 configuration the needles exert a force on the device
8 in an attempt to reform to their unstressed
9 configuration. This causes difficulty in moving the
10 needles within the device.

11

12 According to the present invention there is provided a
13 device for the delivery of a shape memory securing
14 member into a confined space, the device having an exit
15 for the securing member and means to move the securing
16 member through the exit, the device further including a
17 magazine having a plurality of channels each of which
18 can store a securing member.

19

20 Preferably, each securing member is restrained in the
21 device in a first configuration, and upon passing
22 through the exit adopts a second configuration.
23 Also preferably, each channel is separately alignable
24 with the exit.

25

26 One preferred form of magazine is a barrel. The barrel
27 may be rotatable around an axis and the channels may be
28 disposed parallel to said axis or may lie in a helical
29 configuration. This arrangement can be likened to a
30 "revolver barrel" on a firearm.

31

32 The first configuration in which the securing members
33 are held inside the device is optionally straight.
34 However, the securing members may be held in the device
35 in a generally helical configuration. This partially

1 relaxes the securing members and allows the use of high
2 curvature securing members which cannot easily adopt a
3 straightened configuration. The high curvature
4 securing members can form tighter coils when they pass
5 through the exit of the device.

6
7 Preferably, the second configuration is the form of a
8 coil or loop. The coils may be overlapping (like a key
9 ring) or may be partially open. The second
10 configuration is preferentially adopted by the securing
11 member in the absence of any other force. The loops of
12 the second configuration may be round or some other
13 shape such as a rounded oblong or a round cornered
14 triangle. On leaving the device the securing member
15 automatically adopts the second configuration, which is
16 the preferred shape according to the shape memory of
17 the member.

18
19 The channels may include or be in the form of tubes
20 which may themselves move within the device.
21 The securing members may be housed within the tubes.
22 The means to move the securing members may act upon the
23 securing members direct or upon the tubes, to move a
24 tube and a securing member housed therein towards the
25 exit.

26
27 When the securing members are stored within tubes, the
28 tubes can be manipulated within the device more easily
29 than the securing members alone. The tubes may be
30 stored in parallel in the barrel, or may be stored
31 sequentially in a line. The exit of the device may be
32 so arranged as to contain the tubes but allow the
33 securing members to pass from the tubes through the
34 exit.

35

1 The magazine may have indexing means to align a
2 securing member with the exit or with a second channel
3 communicating with the exit. The indexing means may
4 also align the securing member with the means for
5 moving the securing member.

6
7 The magazine may also comprise other means of storing
8 the securing members, such that the securing members
9 are sequentially arranged in a column, line, row or
10 helix, and are sequentially moved to the exit.

11
12 The magazine may be a replaceable element and may
13 contain only sutures or ligatures or a selection of
14 both, optionally in a defined order. The magazine(s)
15 may be colour-coded for ease of use.

16
17 The means for moving the securing members may be
18 disposed between the exit and the securing members,
19 such that the securing members are pulled towards the
20 exit, or alternatively, the securing members may be
21 disposed between the exit and the means for moving the
22 securing members, such that they are pushed towards the
23 exit. In the first arrangement, the means for moving
24 the securing members may comprise an inch worm motor or
25 pinch wheel.

26
27 The exit of the device preferably comprises a tube
28 which is curved in more than one plane. Optionally,
29 the tube is curved once or twice to lie in two or three
30 planes respectively and the exit is located at the end
31 of the tube. The tube may be of circular cross-section
32 or may be of a different cross-section, such as
33 rectangular or oval.

34
35 The exit tube may be sharpened so that it can penetrate

1 tissue before the movement of the securing members
2 through the exit. This may be desirable where the
3 securing members do not easily penetrate the tissue
4 surface. Where tissue penetration by an exit tube is
5 undesirable, the exit tube may be replaced by a tube
6 with a wide or bulbous end. The tube may be part of a
7 detachable assembly that allows re-orientation or
8 extension of the assembly. The assembly can be
9 interchangeable with other forms of assembly to allow
10 the use of eg left and right hand forms and straight
11 forms.

12

13 In an alternative form of the instrument, the exit may
14 be embedded in in a more substantial member such as a
15 half-round continuation of the main instrument body.
16 One or more clamping jaws acting in opposition to the
17 exit (or its more substantial containment structure)
18 may be incorporated in order that it can easily be
19 penetrated by the sutures. The device than has dual
20 suturing and grasping functions. There may be two
21 moving jaws, one behind the other, so that two
22 connective folds of tissue may be grasped for suturing
23 together. Each jaw would have a cutaway to allow
24 passage of the suture. The jaw(s) may be activated
25 from the handle by concentric connections on the
26 instrument axis or in the form of external tubes.

27

28 In another embodiment of the invention, an ultrasonic
29 transducer may be incorporated in or near the exit.
30 This may be used to excite vibrations in the suture in
31 order to make it penetrate tissue more readily.

32

33 In some embodiments, joints between (for example) exit
34 tubes and other tubes in the device may be in the form
35 of collars, where one tube end fits within an end of

1 another tube. This allows the securing members to be
2 moved past joints between tubes more easily.
3 Preferably, the inner faces of all tubes used are
4 smooth.

5
6 The securing members are preferably formed from shape
7 memory alloy such as nickel-titanium (NiTi) alloy and
8 may comprise elongate strips of said alloy which are
9 coiled in the absence of any deforming force. The
10 securing members could also be formed from stainless
11 steel, from another biocompatible material (or coated
12 material) or from material which is resorbable by the
13 body.

14
15 The securing members may be in the form of sutures
16 which have at least one sharp end or may be in the form
17 of ligatures having blunt ends. In the case of the
18 ligature, the surgeon holds the exit of the device next
19 to the body part to be ligated (eg, a blood vessel) and
20 the ligature will wrap itself around the body part as
21 it is expelled. Securing members in the form of
22 sutures are formed with a sharp point at the leading
23 end. The surgeon then places the device so that the
24 point of the exiting sutures penetrates the tissue(s)
25 to be sutured. The suture then re-coils upon exit and
26 creates a join in the tissue(s). Also in the case of a
27 suture, the exit tube may be required to deliver the
28 suture in a plane normal to the axis of the instrument.

29
30 A further advantage of the delivery device according to
31 one embodiment of the present invention is that it can
32 store several sutures or ligatures to allow multiple
33 placements without the need to withdraw the instrument
34 from the patient.

35

1 According to a second aspect of the present invention
2 there is provided a device for the delivery of a shape
3 memory securing member into a confined space, the
4 device having an exit for the securing member, means to
5 move the securing member through the exit, and means
6 for cutting the securing member, preferably once a
7 portion thereof has been passed through the exit.

8

9 Preferably, upon leaving the device, the expelled
10 portion of the securing member automatically adopts a
11 configuration in accordance with its shape memory.

12

13 The device according to the second aspect of the
14 invention preferably contains a securing member in a
15 continuous form, such as a roll, helix or coil. The
16 configuration of the securing member preferably changes
17 as it passes between the interior and exterior of the
18 device. Thus when the securing member is in the form
19 of a high-curvature coil of shape memory alloy, it can
20 be maintained in a relaxed state (at or near its
21 preferred shape according to its memory) when stored
22 within the device, and need only be subjected to stress
23 when its configuration changes upon leaving the device.

24

25 The means for cutting the securing member is preferably
26 disposed adjacent the exit so as to cut the securing
27 member as it leaves the device. The means for cutting
28 and the means for expelling may be provided by a single
29 element, for example, a pinch wheel. The means for
30 cutting may include means for sharpening the end of the
31 securing member left inside the device.

32

33 The present invention further provides a shape memory
34 securing member for use in a device as defined above,
35 the securing member having the form of a loop, coil or

1 a helix in the absence of any force acting upon it.

2

3 Embodiments of the present invention will now be
4 described by way of example only and with reference to
5 the accompanying drawings in which:

6

7 Fig. 1a shows a top view of a delivery device;

8 Fig. 1b shows a side view of the device of Fig.

9 1a;

10 Fig. 1c shows an end view on A of Fig. 1a.

11 Fig. 2a shows an end view of a barrel of the
12 device of Fig. 1;

13 Fig. 2b shows a longitudinal sectional view along
14 line B-B through the barrel of Fig. 2a;

15 Fig. 2c shows the opposite end view of the barrel
16 of Fig. 2a;

17 Fig. 3 shows a detailed sectional view of the end
18 of the device of Fig. 1 with the barrel of Fig. 2a
19 in place;

20 Fig. 4a shows a side view of the device of Fig. 1
21 with the barrel of Fig. 2a removed; and

22 Figs 4b and 4c show one end of second and third
23 devices with an embedded exit and with a jaw for
24 holding tissue against the exit.

25

26 Referring to Fig. 1a, b and c, a delivery device 1 has
27 a housing 5 in the form of an elongate tube of an
28 exemplary diameter of 10mm which has at one end a
29 pistol grip 10 and at the other end a cut away section
30 6. The cut-away section 6 is adapted to accept a
31 magazine in the form of a barrel 15 which generally
32 conforms to the outer shape of the housing 5 so as to
33 fit into the cut-away section 6.

34

35 The housing 5 has a exit tube 20 attached to one end

1 thereof and communicating with the interior of the
2 housing 5.

3
4 The exit tube 20 curves twice and has an exit 21 which
5 faces one side of the device 1. The embodiment shown
6 is one adapted for delivery of sutures and delivers the
7 suture in a plane normal to the axis of the device.
8 The device of the invention may also be used for
9 delivering ligatures and in such a case, the exit tube
10 preferably curves once only and the second curve shown
11 in the exit tube 20 is not required.

12
13 Referring now to Fig. 2a, b and c, the barrel 15
14 comprises an inner hollow cylinder 15a and an outer
15 hollow cylinder 15b. The outer cylinder 15b has twelve
16 grooves 25 on the inner surface thereof which extend
17 along the length of the cylinder 15b. The grooves 25
18 are preferably formed by wire erosion and in the
19 example shown have a diameter of 0.3mm. The two
20 cylinders 15a and 15b can be fitted together as shown
21 in the drawings such that the grooves 25 form channels
22 from one end of the barrel 15 to the other. Securing
23 members are disposed in the grooves 25 in use of the
24 device. The securing members are typically formed from
25 shape memory alloy wire such as NiTi wire and in the
26 present example, are 0.25mm in diameter. The inner
27 cylinder 15a has an axial bore 28 extending
28 therethrough and in one end face 12 has indentations 30
29 which extend a short distance into the cylinder 15a in
30 an axial direction. In the opposite end face of the
31 inner cylinder 15a is a slot 32 which intersects with
32 the end of the bore 28.

33
34 Referring now to Fig. 3, the end of the device 1 which
35 holds the barrel 15 has an end stop 35 located after

1 the cut-away section 6. The end stop has an axial
2 indentation or bore 29 on the internal face extending
3 at least partially along the axis of the end stop 35
4 and which is co-axial with bore 28 when the barrel 15
5 is in place in the cut-away section 6. The end stop 35
6 also has an annular arrangement of twelve bores 38 in
7 its inner face in which are located springs 40 and ball
8 bearings 42. The springs 40 bear on portions 35a of
9 the outer wall of end stop 35 and exert force on the
10 ball bearing 42 so as to expel them from the bores 38
11 in the direction of the pistol grip 10. Typically, the
12 ball bearings 42 are restrained from leaving the bores
13 38 entirely and may be held captive on the springs 38
14 or embedded in the end stop 35.

15

16 When the barrel 15 is in place in the cut-away section
17 6, the ball bearings 42 are forced out of the bores 38
18 and engage with the indentations 30 in the barrel 15.
19 Thus a series of twelve detent positions is
20 established..

21

22 An axle 50 (shown in Fig. 4a) is withdrawn from the
23 cut-away section 6 by a handle 51. The barrel 15 (not
24 shown in Fig 4a) is loaded with twelve securing members
25 such as sutures formed from NiTi shape memory alloy,
26 and is located in the cut-away section 6. The sutures
27 are held in a generally straightened configuration in
28 the grooves 25 of the barrel 15. The axle 50 is then
29 moved towards the end stop 35 by manipulating the
30 handle 51 such that the axle 50 passes through the bore
31 28 and engages in the axial bore 29 in the end stop 35.
32 Additionally a pair of projections 52 on the axle 50
33 are disposed in the slot 32 on the barrel 15 thereby
34 locking the barrel 15 against axial rotation with
35 respect to the axle 50. The barrel 15 is thereby

1 locked in place in the cut-away section 6 and can be
2 rotated through its detent positions by manipulation of
3 the axle 50. The detent positions are held by the
4 action of the ball bearings 42 engaging in the
5 indentations 30.

6
7 The barrel 15 is released by sliding back the handle 51
8 so as to disengage the projections 52 from the slots 32
9 and the axle 50 from the bore 28. The barrel 15 can
10 then be removed and reloaded or replaced with one
11 already loaded.

12
13 In each of the detent positions a respective one of the
14 grooves 25 is in line with the exit tube 20, thus
15 allowing a securing member (not shown) such as a suture
16 or ligature to be expelled from the groove 25 through
17 the exit tube 20 and out of the exit 21.

18
19 The housing 5 also includes a flexible push wire 55
20 which is supported in a guide tube 58. The end of the
21 guide tube 58 is in line with the exit tube 20 and with
22 a respective one of the grooves 25 when the barrel 15
23 is in a detent position.

24
25 The push wire 55 is slidable in the guide tube and can
26 be moved so as to protrude into a respective one of the
27 grooves 25 when the barrel 15 is in a detent position
28 in the cut-away section 6. The push wire 55 is clamped
29 by a sliding clamp 60 which is moved by a rack and
30 pinion mechanism 65 located in the pistol grip 10. The
31 rack and pinion mechanism 65 is in turn activated by a
32 trigger 70.

33
34 The rack and pinion mechanism 65 has gears which
35 increase the movement of the trigger 70 and reverse its

1 direction so as to advance the clamp 60 towards the
2 barrel 15 located in the cut-away section 6.

3
4 Movement of the push wire 55 along the support tube 58
5 and into the groove 25 expels a securing member located
6 therein from the exit tube 20. Thus actuation of the
7 trigger 70 causes the push wire 55 to push a securing
8 member from one of the grooves 25 out of the exit tube
9 20. Upon leaving the exit tube 20, the securing member
10 no longer has any force acting upon it to maintain it
11 in its straightened configuration, and it re-coils into
12 its preferred shape memory configuration of a loop or
13 coil.

14
15 The movement of the trigger 70 could also cause the
16 barrel 5 to rotate through one detent position so that
17 the next groove 25 is aligned with the exit tube 20 and
18 the support tube 58. The barrel-rotation mechanism
19 (not shown) is similar to the mechanisms found in some
20 ball-point pens.

21
22 Different barrels may hold different securing members
23 for different purposes, or a single barrel may hold a
24 number of different securing members.

25
26 Figure 4b shows the end of a second device according to
27 the present invention, having its exit 72 embedded in a
28 semi-circular extension 74 of the main body of the
29 device 76. Adjacent the exit 72 is a moveable clamping
30 jaw 78, in which is a cutaway 80 through which an
31 exiting securing member can pass. Tissue can be
32 grasped between the exit 72 and the jaw 78. Figure 4c
33 shows a third device having two moveable jaws 82
34 opposite the device exit 84.

35

1 Modifications and improvements may be incorporated
2 without departing from the scope of the invention.
3

1 **CLAIMS**

2

3

4 1. A device for the delivery of a shape memory
5 securing member into a confined space, the device
6 having an exit for the securing member and means
7 to move the securing member through the exit, the
8 device further including a magazine having a
9 plurality of channels each of which can store a
10 securing member.

11

12 2. A device as claimed in Claim 1 wherein each
13 channel of the magazine is separately alignable
14 with the exit.

15

16 3. A device as claimed in Claim 1 or Claim 2 wherein
17 the or each securing member is restrained in the
18 device in a first configuration, and upon passing
19 through the exit adopts a second configuration.

20

21 4. A device as claimed in any one of Claims 1 to 3
22 wherein the or each securing member is made from
23 nickel-titanium alloy or stainless steel.

24

25 5. A device as claimed in any one of the preceding
26 Claims wherein the magazine is a barrel.

27

28 6. A device as claimed in Claim 5 wherein the barrel
29 is rotatable about an axis.

30

31 7. A device as claimed in Claim 6 wherein the
32 channels are arranged along the barrel and
33 disposed parallel with the axis.

34

35 8. A device as claimed in Claim 6 wherein the
36 channels are arranged along the barrel and

- 1 disposed in a helical configuration to the axis.
2
- 3 9. A device as claimed in any one of Claims 3 to 8
4 wherein the second configuration is the form of a
5 coil or loop.
6
- 7 10. A device as claimed in any one of Claims 3 to 9
8 wherein the second configuration of the securing
9 member is the preferred shape according to the
10 shape memory of the securing member.
11
- 12 11. A device as claimed in any one of the preceding
13 Claims wherein the magazine is lockable within the
14 device.
15
- 16 12. A device as claimed in any one of the preceding
17 Claims wherein the magazine is loaded with a
18 plurality of securing members.
19
- 20 13. A device as claimed in any one of the preceding
21 Claims wherein the channels include or be in the
22 form of tubes.
23
- 24 14. A device as claimed in any one of the preceding
25 Claims wherein the magazine has indexing means to
26 align a securing member with the exit or with a
27 second channel communicating with the exit.
28
- 29 15. A device as claimed in Claim 14 wherein the
30 indexing means aligns the securing member with the
31 means for moving the securing member.
32
- 33 16. A device as claimed in any one of the preceding
34 Claims wherein the magazine is removable from the
35 device.
36

- 1 17. A device as claimed in any one of the preceding
2 Claims wherein the means for moving a securing
3 member is disposed between the exit and the or
4 each securing member.
5
- 6 18. A device as claimed in any one of Claims 1 to 16
7 wherein the or each securing member is disposed
8 between the exit and the means for moving the
9 securing member.
10
- 11 19. A device as claimed in Claim 18 wherein the means
12 for moving the securing member is a push wire.
13
- 14 20. A device as claimed in Claim 19 wherein the push
15 wire is flexible and slidable in a guide tube.
16
- 17 21. A device as claimed in any one of the preceding
18 Claims in which the exit comprises a tube.
19
- 20 22. A device as claimed in Claim 21 wherein the free
21 end of the tube is sharpened.
22
- 23 23. A device as claimed in Claim 21 or Claim 22
24 wherein the tube is curved.
25
- 26 24. A device as claimed in any one of Claims 21 to 23
27 wherein the tube is detachable.
28
- 29 25. A device as claimed in any one of the preceding
30 Claims wherein the device includes one or more
31 clamping jaws acting in opposition to the exit.
32
- 33 26. A device as claimed in Claim 25 wherein one or
34 more of the jaws is moveable, and wherein a
35 securing member is passable through one or more of
36 the jaws.

- 1 27. A device as claimed in any one of the preceding
2 Claims wherein the device includes an ultrasonic
3 transducer located in or near the exit.
4
- 5 28. A device for the delivery of a shape memory
6 securing member into a confined space, the device
7 having an exit for the securing member, means to
8 move the securing member through the exit, and
9 means for cutting the securing member or a portion
10 of the securing member that has passed through the
11 exit.
12
- 13 29. A device as claimed in Claim 28 wherein the
14 expelled portion of the securing member
15 automatically adopts a configuration in accordance
16 with its shape memory.
17
- 18 30. A device as claimed in Claim 29 wherein the
19 adopted configuration is a coil or loop.
20
- 21 31. A device as claimed in Claim 28, 29 or Claim 30
22 wherein the securing member in the device is in a
23 continuous form.
24
- 25 32. A device as claimed in Claim 31 wherein the
26 configuration of the securing member changes as it
27 passes between the interior and exterior of the
28 device.
29
- 30 33. A device as claimed in any one of the Claims 28 to
31 32 wherein the means for cutting the securing
32 member is disposed adjacent to the exit.
33
- 34 34. A device for the delivery of a shape memory
35 securing member into a confined space, the device
36 having an exit for the securing member and means

1 to move the securing member through the exit,
2 wherein the securing member is stored in the
3 device in an arcuate configuration.
4

5 35. A device as claimed in Claim 34 wherein the
6 securing member is stored in the device in a
7 helical configuration.
8

9 36. A device as claimed in any one of preceding Claims
10 for use as a surgical instrument.
11

12 37. A device as claimed in Claim 36 wherein the
13 securing member is a suture or a ligature.
14

15 38. A device as claimed in any one of the preceding
16 Claims wherein the device includes a handle and
17 includes a trigger means to operate the means to
18 move the securing member.
19

20 39. A shape memory securing member for use in a device
21 as claimed in Claims 1 to 38.
22

23 40. A method of delivering a securing member into a
24 confined space using a device as defined in Claims
25 1 to 38 wherein at least the exit of the device is
26 located within the confined space, and the means
27 to move the securing member is activated to
28 deliver the securing member from the device
29 through the exit.
30

31 41. A method as claimed in Claim 40 wherein the
32 securing member changes from a first configuration
33 in the device to a second configuration upon
34 passing through the exit.
35

36 42. A device for the delivery of a sharp memory

1 securing member into a confined space
2 substantially as herein defined and with reference
3 to Figs 1a, b, c, 2a, b, c, 3 and 4a.
4

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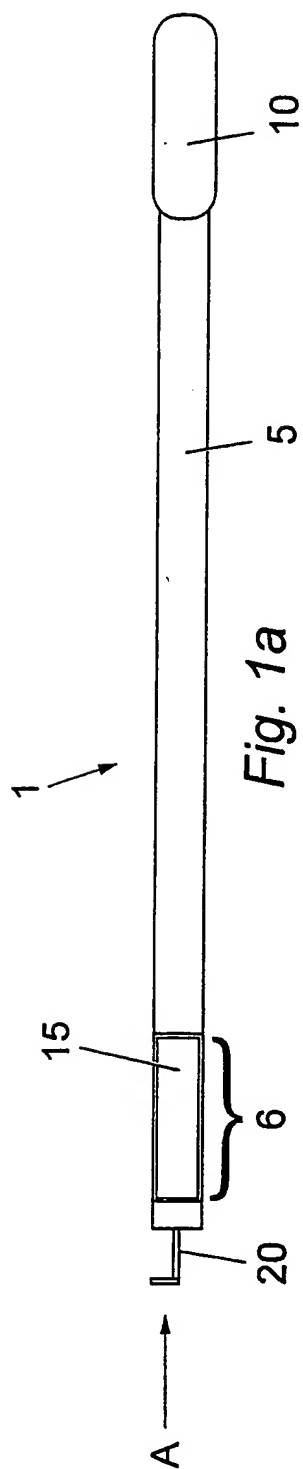


Fig. 1a

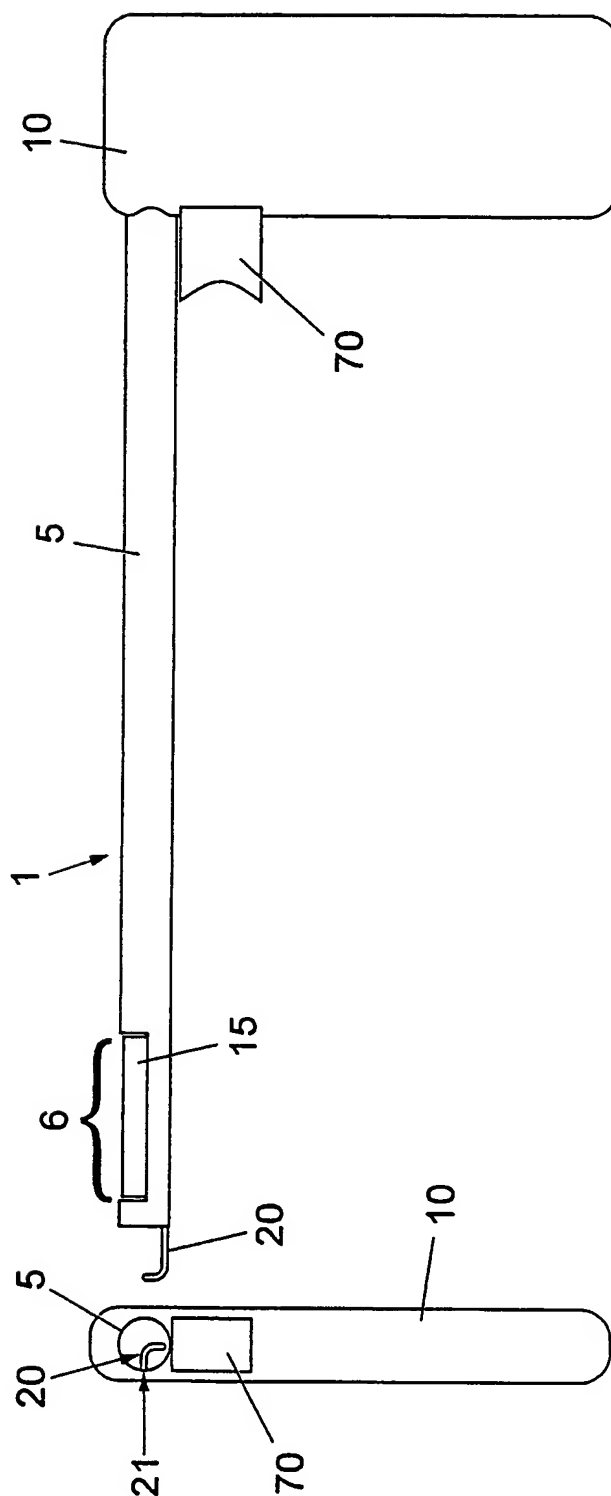


Fig. 1b

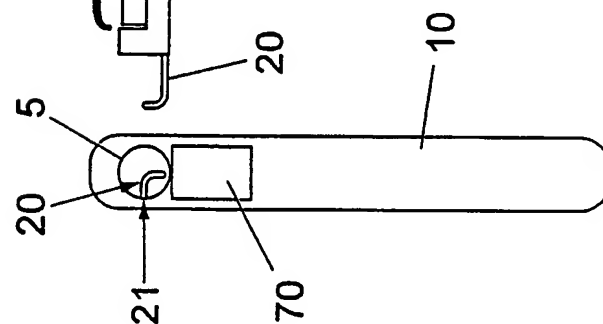
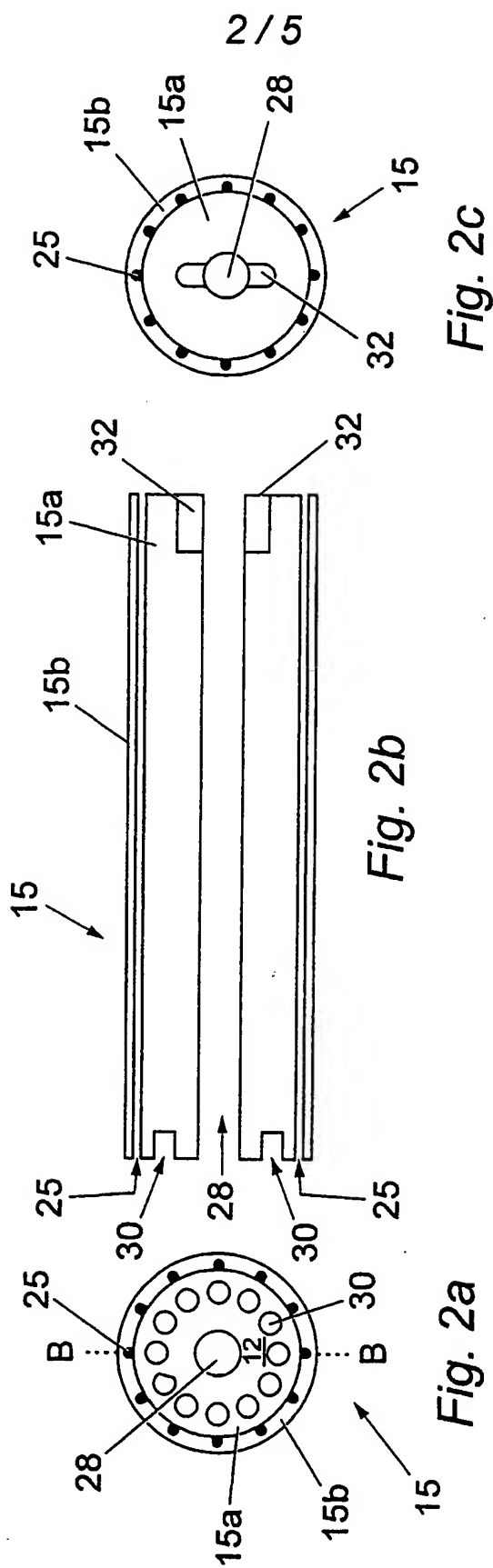


Fig. 1c



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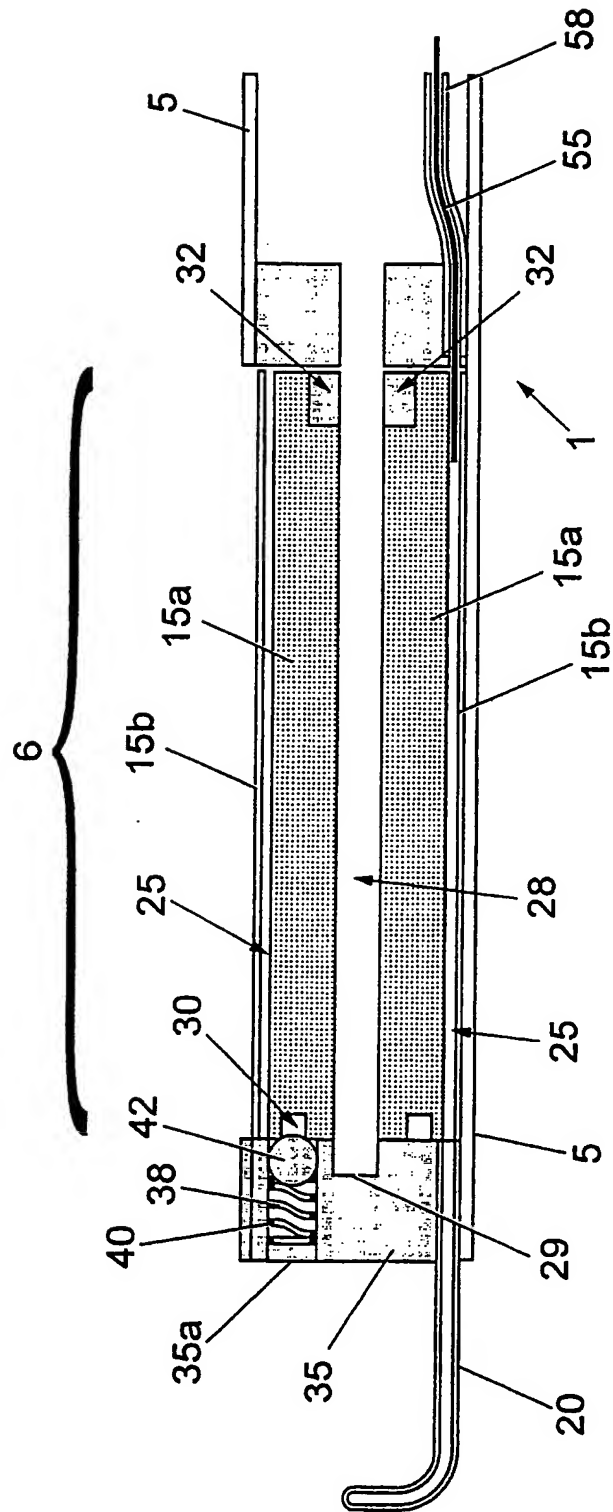


Fig. 3

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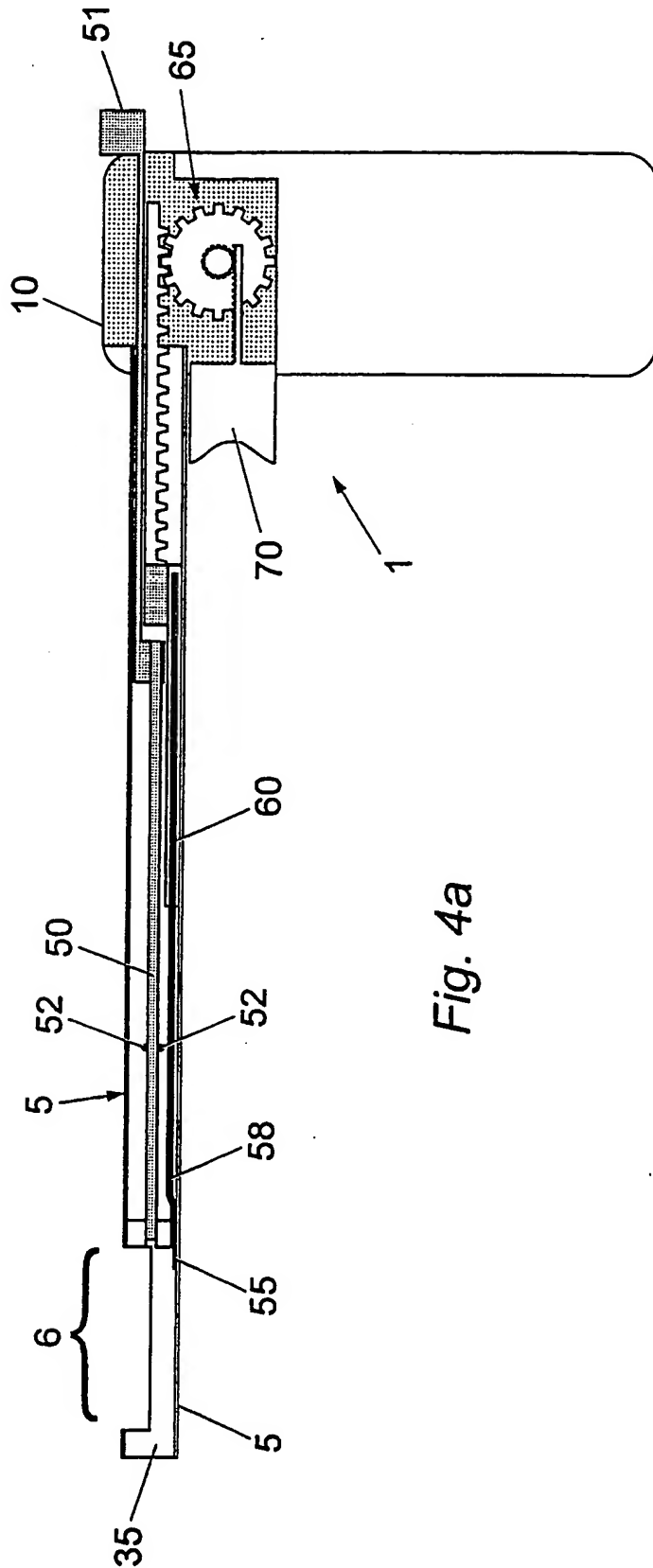


Fig. 4a

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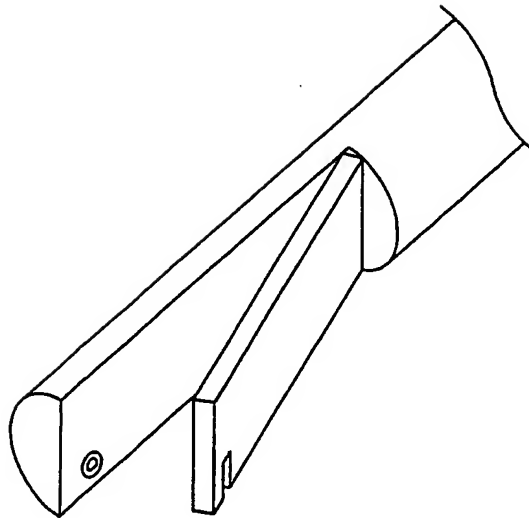


Fig. 4b

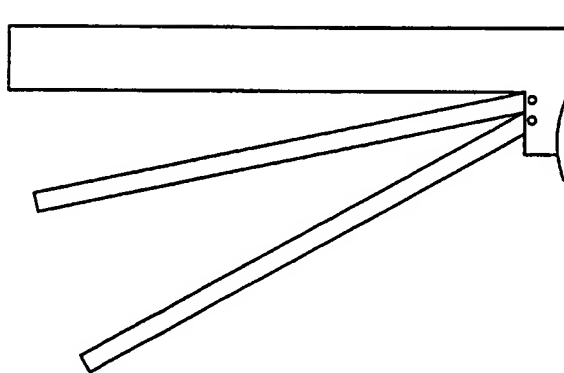


Fig. 4c

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